Standardize on the proven solution for active hemostasis.

Avitene™
Microfibrillar Collagen Hemostat

BIOSURGERY
Proven Science. Excellent Outcomes.
The Power of Avitene™ Hemostats

Avitene™ Microfibrillar Collagen Hemostat is an active collagen hemostat, proven to accelerate clot formation. Collagen accelerates clot formation by enhancing platelet aggregation and the release of proteins to form fibrin, resulting in hemostasis.

- Active absorbable topical hemostatic agent
- 100% collagen: potentiates patient’s own clotting mechanism
- Trusted by surgeons for its safety and efficacy for over 40 years
- A collagen hemostat acceptable for all procedures where a topical hemostat is indicated, including urologic and neurosurgery
- Easy to use
- Over 200 clinical papers

Outline of the clotting mechanism

- Injury to blood vessel
- Blood is exposed to collagen, attracting platelets and releasing proteins
- Prothrombin is converted to thrombin
- Thrombin converts fibrinogen to fibrin
- Platelet plug
- Vasoconstriction
- Clot

Avitene™ Flour

- Effective in controlling arterial bleeding
- Conforms and adheres to irregular spaces
- Easy removal with irrigation and suction

Avitene™ Sheets (Non-woven web)

- Avitene™ Sheets provide the same efficacy expected from Avitene™ Flour
- Cut to any shape or size
- Clings tenaciously to hemorrhage
- Remove with irrigation and suction, minimizing the need to leave foreign material in situation
- Ideal for use on flat surfaces or to wrap vessels and anastomosis sites

EndoAvitene™ Collagen Hemostat

- Preloaded sheets for endoscopic delivery
- 5 mm and 10 mm diameters pass easily through standard trocars and cannulae
- Avoid thermal damage to tissue, primary and adjacent structures
- Avoid converting to emergency open procedures
**AVITENE™ Microfibrillar Collagen Hemostat and AVITENE™ ULTRAFOAM™ Collagen Sponge**

**Indications**
AVITENE™ (MCH) is used in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

**Contraindications**
AVITENE™ (MCH) should not be used in the closure of skin incisions as it may interfere with the healing of the skin edges. This is due to simple mechanical interposition of dry collagen and not to any intrinsic interference with wound healing. By filling porosities of cancellous bone, MCH may significantly reduce the bond strength of methylmethacrylate adhesives. MCH should not, therefore, be employed on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

**Warnings**
AVITENE™ (MCH) is inactivated by autoclaving. Ethylene oxide reacts with bound hydrochloric acid to form ethylene chlorohydrin. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. MCH is not for injection or intracaval use. Moistening MCH or wetting with saline or thrombin impairs its hemostatic efficacy. It should be used dry. Discard any unused portion. As with any foreign substance, use in contaminated wounds may enhance infection.

**Precautions**
Only that amount of AVITENE™ (MCH) necessary to produce hemostasis should be used. After several minutes, excess material should be removed; this is usually possible without the reintitation of active bleeding. Any excess AVITENE™ (MCH) not removed at the time of surgery may either present itself as a (recurring) mass or a (space occupying) lesion or it may lead to a foreign body reaction that may present with or without clinical signs and symptoms as a recurring mass or lesion or postoperative abscess formation upon imaging. Imaging may initially not be capable of distinguishing the difference. Removal of excess material, ideally performed upon conclusion of the initial procedure, typically resolves all signs and symptoms. Failure to remove excess MCH may result in bowel adhesion or mechanical pressure sufficient to compromise the ureter. In otolaryngological surgery, precautions against aspiration should include removal of all excess dry material and thorough irrigation of the pharynx. MCH contains a low, but detectable, level of intercalated bovine serum protein which reacts immunologically as does beef serum albumin. Increases in anti-BSA titer have been observed following treatment with MCH. About two-thirds of individuals exhibit antibody titers because of ingestion of food products of bovine origin. Intradermal skin tests have occasionally shown a weak positive reaction to BSA or MCH but these have not been correlated with IgG titers to BSA. Tests have failed to demonstrate clinically significant elicitation of antibodies of the IgG class against BSA following MCH therapy. Care should be exercised to avoid spillage on nonbleeding surfaces particularly in abdominal or thoracic viscera. AVITENE™ (MCH) should not be used in conjunction with autologous blood salvage circuits, as AVITENE™ may pass through the filters of such systems. It has been suggested that fragments of MCH may pass through filters of blood scavenging systems, therefore the reintroduction of blood from operative sites treated with MCH should be avoided. Teratological studies in rats and rabbits have revealed no harm to the animal fetus. There are no well-controlled studies in pregnant women, therefore, MCH should be used in pregnant women only when clearly needed. AVITENE™ non-woven web should not be used as a surface dressing except for immediate control of bleeding. Avoid packing AVITENE™ tightly in cavities, especially within the bony enclosure of the CNS or within other relatively rigid cavities where swelling may interfere with normal function or possibly cause necrosis. AVITENE™ is not recommended for use in patients sensitive to bovine derived collagen.

**Adverse Reactions**
The most serious adverse reactions reported which may be related to the use of AVITENE™ (MCH) are potentiation of infection including abscess formation, hematoma, wound dehiscence and mediastinitis. Other reported adverse reactions possibly related are adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (report of a single case). The use of MCH in dental extraction sockets has been reported to increase the incidence of alveolalgia. Transient laryngospasm due to aspiration of dry material has been reported following use of MCH in tonsillectomy.

---

**SyringeAVITENE™ Collagen Hemostat**
- Preloaded 1 gram SyringeAVITENE™ Collagen Flour used in trauma, oncology, general, and cardiovascular surgery

**AVITENE™ ULTRAFOAM™ Collagen Sponge**
- Easy, effective solution for hemostasis
- In an animal study, ULTRAFOAM™ Collagen without thrombin was as effective as Gelfoam® Sponge with thrombin
  - Reduced thrombin usage may lower cost
  - Soft, pliable sponge is ready-to-use out of the package
  - No soaking, no waste
  - Does not swell
Contraindications
Avitene™ UltraFoam™ sponge should not be used in the closure of skin incisions as it may interfere with the healing of the skin edges. This is due to simple mechanical interposition of dry collagen and not due to any intrinsic interference with wound healing.

It has been reported with other collagen hemostatic agents, that by filling porosities of cancellous bone, they may significantly reduce the bond strength of methyl methacrylate adhesives. Avitene™ UltraFoam™ sponge should not, therefore, be employed on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

Warnings
Avitene™ UltraFoam™ sponge is inactivated by autoclaving.

Ethylene oxide reacts withbound hydrochloric acid to form ethylene chlorohydrin.

This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. Opened, unused product should be discarded.

As with any foreign substance, use of Avitene™ UltraFoam™ sponge in contaminated wounds may enhance infection.

Avitene™ UltraFoam™ sponge should not be used in instances of pumping arterial hemorrhage.

It should not be used where blood or other fluids have pooled, or in cases where the point of hemorrhage is submerged as it may mask an underlying source of bleeding, resulting in hematoma.

Avitene™ UltraFoam™ sponge will not act as a tampon or plug in a bleeding site, nor will it close off an area of blood collecting behind a tampon. Avitene™ UltraFoam™ sponge is not intended to treat systemic coagulation disorders. Not for injection, intraocular or intravascular use.

Precautions
Avitene™ UltraFoam™ sponge, like other collagen hemostats, should not be left in infected sites or on infected surfaces.

As with other hemostatic agents, it is not recommended for use in persons with known sensitivity to material of bovine origin.

Any excess Avitene™ UltraFoam™ not removed at the time of surgery may either present itself as a (recurring) mass or a (space occupying) lesion or it may lead to a foreign body reaction that may present with or without clinical signs and symptoms as a recurring mass or lesion or postoperative abscess formation upon imaging. Imaging may initially not be capable of distinguishing the difference. Removal of excess material, ideally performed upon conclusion of the initial procedure, typically resolves all signs and symptoms.

Microfibrillar Collagen Hemostat (MCH) contains a low, but detectable, level of intercalated bovine serum protein which reacts immunologically as does beef serum albumin. Increases in anti-BSA titer have been observed following treatment with MCH. About two-thirds of individuals exhibit antibody titers because of ingestion of food products of bovine origin. Intradermal skin tests have occasionally shown a weak positive reaction to BSA or MCH but these have not been correlated with IgG titers to BSA. Tests have failed to demonstrate clinically significant elicitation of antibodies of the IgG class against BSA following MCH therapy.

When placed into cavities or closed spaces, care should be exercised to avoid overpacking Avitene™ UltraFoam™ sponge as it may press against neighboring structures.

The safety of this product has not been established in children or in pregnant women; therefore, Avitene™ UltraFoam™ sponge should only be used after an evaluation of the relative benefits and risks clearly warrant its use.

Adverse Reactions
The most serious adverse reactions reported, which may be related to the use of other collagen products, are potentiation of infection including abscess formation, hematoma, wound dehiscence and mediastinitis.

Other reported adverse reactions possibly related are adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (report of a single case), and increased incidence of alveolalgia when used for packing of dental extraction sockets.

To order, call your local representative or our customer service department at 1.800.556.6275 or visit us on the web at www.davol.com

For 24 hour dedicated technical and clinical support for Avitene™ call 1.800.562.0027

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

Avitene, Bard, Davol, EndoAvitene, SyringeAvitene and UltraFoam are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate. All other trademarks are property of their respective owners.

† A Comparison of Avitene™ UltraFoam™ versus Gelfoam® with and without Thrombin to Effectively Control Bleeding, Raymond Connolly, Ph.D., Surgical Research Laboratory, New England Medical Center, Boston, MA.